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ORIGINAL ARTICLE

# Clinical study on the treatment of chronic heart failure with a novel D-shant atrium shunt device

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## Abstract

**Background** Atrial septal shunt devices might improve hospitalizations and also prognosis in heart failure with increased pulmonary pressures due to left heart diseases. In recent years, atrial shunt devices have been used for the treatment of chronic heart failure, but there remains a lack of clinical experience. This study aimed to analyse the therapeutic effect of a novel type of atrial shunt on chronic heart failure.

**Methods and results** From May 2020 to September 2020, six patients who were diagnosed with chronic heart failure and completed percutaneous D-shant atrium shunt device implantation in the Department of Cardiovascular Surgery, Union Hospital, were retrospectively included. The shunt location was evaluated by echocardiography and digital subtraction angiography. Heart function was evaluated by New York Heart Association functional class. Echocardiography was used to measure the diameter of the new chamber and ventricle, and to evaluate the degree of mitral and tricuspid regurgitation. Before operation and 6 months after operation, left atrial end-diastolic volume, right atrial end-diastolic volume, left ventricular end-diastolic volume, and right ventricular end-diastolic volume were measured by magnetic resonance imaging. Left ventricular ejection fractions and right ventricular ejection fractions were calculated. Haemodynamic indexes of right heart catheterization and clinical cardiac function indexes were collected and compared before and 6 months after shunt implantation. All six patients completed percutaneous shunt device implantation. Echocardiography and digital subtraction angiography showed that the shunt device was correctly positioned and unobstructed in all patients. Echocardiography revealed that the left ventricular diameter decreased significantly from 6.40 ± 0.57 mm to 5.03 ± 0.73 mm ($P < 0.05$). There was an obvious decrease in mitral regurgitation. Magnetic resonance imaging showed a reduction in the volume of the left ventricle (182.00 ± 27.02 mL vs. 125.75 ± 16.11 mL, $P < 0.05$). Cardiac catheter examination showed the mean left atrium pressure or pulmonary capillary wedge pressure decreased postoperatively (31.83 ± 11.55 vs. 18.00 ± 5.51 mmHg, $P < 0.05$). There was also obvious improvement in clinical indicators of cardiac function at 6 months after implantation.

**Conclusions** This novel D-shant atrium shunt device revealed maintained good function, no dislodgement and no paradoxical emboli. After implantation, functional mitral regurgitation in all patients with heart failure with reduced ejection fraction improved.

**Keywords** Atrial shunt device; Heart failure; Ejection fraction

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## Introduction

Heart failure is a common manifestation of various chronic structural or non-structural heart diseases in the later stage. It was reported that there were more than 6 million cases of heart failure in the United States, and the incidence rate of heart failure is increasing with the development of ageing population.[1] The most common cause of heart failure is left

heart failure. The main clinical manifestation is progressive exertional dyspnoea. The reason is that the increase of left heart preload and the increase of left atrial and pulmonary venous pressure lead to pulmonary congestion.[2] Delaying or preventing heart failure is becoming more and more important in patients prone to heart failure and the best evidence-based drug therapy (including inhibitors of the renin–angiotensin–aldosterone system and β blockers) can achieve ideal efficacy only when they are best implemented.[3] Although there are multiple types of drugs for systemic treatment of chronic heart failure, their efficacy is still limited, and the 5 year mortality rate is still as high as 45%–60%.[4] It was reported that patients with heart failure with reduced ejection fraction (HFrEF), heart failure with midrange ejection fraction, and heart failure with preserved ejection fraction have similar mortality rates and prognoses.[5]

In recent years, some assistive devices have appeared in addition to standardized drug therapy, including implantable cardioverter defibrillator[6] and cardiac resynchronization therapy.[7] However, left heart-assisted devices such as implantable cardioverter defibrillators and Cardiac Resynchronization Therapy-Defibrillators have been used to treat HFrEF patients who are inadequately controlled by pharmacotherapy, their clinical application is rather limited.[8] Over recent years, atrial shunt devices have been used for the treatment of chronic heart failure, but there remains a lack of clinical experience.[9–13] Hence, the aim of the present study was to report the first application of the atrial shunt device D-shant in the treatment of 6 patients and provide clinical basis for the application of new atrial shunt device.

# Materials and methods

## Subjects

In this retrospective study, a total of six patients with heart failure admitted to the Wuhan Union Hospital of Huazhong University of Science and Technology from May 2020 to September 2020 were included. Inclusive criteria were as follows: (1) age ≥18 years old; (2) patient who signed a consent form with fully comprehending the intended procedure, complications and outcomes and was willing to follow the clinical investigation and follow-up procedures; (3) New York Heart Association (NYHA)[14] Class II–NYHA Class (ambulatory) IV patients with chronic heart failure who still had symptoms after at least 4 weeks of standardized drug treatment[15]; (4) mean pulmonary capillary wedge pressure/mean left atrial pressure–mean right atrial pressure ≥5 mmHg; (5) patients who had received comprehensive pharmacotherapy including angiotensin receptor neprilysin inhibitors (ARNI), aldosterone receptor antagonists, and β-receptor blockers for heart failure for at least 6 months prior to hospitalization; (6) having performed multimodality imaging studies, including echocardiography, cardiac computed tomography angiography, and magnetic resonance imaging (MRI). Exclusion criteria are as follows: (1) severe liver and kidney damage; (2) accompanied by autoimmune diseases, or accompanied by other serious systemic diseases; (3) recent history of surgery and severe trauma.

This study was approved by the National Medical Products Administration (NMPA) and Institutional Review Board (IRB) of Wuhan Union Hospital of Huazhong University of Science and Technology (approval no. 20200165). All participants provided written informed consent.

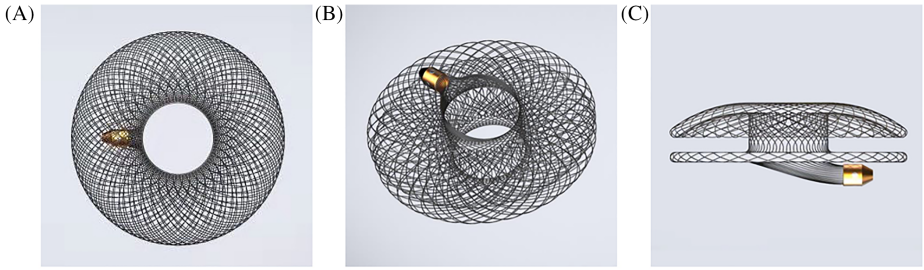
## Design of D-shant atrium shunt device

D-shant atrium shunt device was a double disc and buckle-shaped mesh plug made of nickel-titanium alloy (Wuhan Vickor Medical Technology Co., Ltd). The properties of this type of shape memory metal allowed the device to achieve the best fit with the interatrial septum. The device was connected to the delivery wirerope through a stainless-steel nut, and device implantation, release, and unloading were achieved using a 7-9F introducer, which was similar to the Amplatzer occluder. The nut had a transverse and eccentric design and was attached to the plate, which allowed the device to be retrieved and changed, including snare retrieval of an inadvertently detached device. The lumbar hole was designed with a unique reinforced support to avoid excessive compression on the aperture by interatrial septal tissues and to preserve the ability for further intervention on the aperture, thus allowing redilation of the hole in the distant future.

The D-shant atrium shunt device was designed in four sizes according to clinical needs: 4, 6, 8, and 10 mm, which corresponded to the disc diameter of the device: 16, 20, 24, and 28 mm. The loading sheath was repeatedly flushed using cold normal saline when the equipment was assembled *ex vivo* to ensure that the loading sheath was filled with normal saline and free of air. The structure of the D-shant atrium shunt device was shown in *Figure 1*.

The selection of device size for each patient mainly depends on hydrodynamic indexes obtained by preoperative right heart catheterization. The size of the shunt's aperture was inversely proportional to the pressure difference between the left atrium and the right atrium and was proportional to the patient's body surface area. Moreover, the evaluation of the optimal diameter of the device aperture and selection methods was still under evaluation. In this preliminary study, we mainly referred to the pressure gradient between the left and right atria, measured during right heart catheterization and the body surface of patients. In general, the greater the inter-atrial pressure gradient, and the smaller the body surface, the smaller the fenestration diameter of

**Figure 1** Appearance of D-shant atrium shunt device. (A) Top view plane. (B) Squint plane. (C) Side view plane.




the device was, and *vice versa*. Haemodynamic parameters were measured once more after device implantation. The ideal fenestration diameter should reduce the pressure of the left atrium by at least 30% and maintain pulmonary-to-systemic blood flow ratio (Qp/Qs) between 1.2 and 1.4, and a left-to-right pressure gradient of at least 2–5 mmHg.[16] This was key to assuring long-term patency of the shunt in patients and minimizing the occurrence of right heart failure and paradoxical embolism. If the ideal range was not reached, the device could be retrieved, and appropriate shunt devices could be reselected.

## Interventional procedure

An interventional operation was performed under regional anaesthesia. Transesophageal echocardiography or intracardiac ultrasonography was an important postoperative evaluation method. Therefore, patients were fasted for 6 h before interventional operation. Systemic haemodynamic evaluation was undertaken both before and after intervention to determine the optimal shunt size for patients. Pressure values obtained during catheterization included pressures of the right atrium, right ventricle, pulmonary artery, pulmonary arteriole wedge, left atrium, left ventricle, aorta, and the end-diastolic pressure of the left ventricle. In addition, total lung resistance, pulmonary vascular resistance, systemic circulation resistance, blood flow of the pulmonary and systemic circulation, cardiac index, systemic-to-pulmonary shunt, and the ratio of systemic-to pulmonary resistance were measured based on blood gas analysis or haemodynamic monitoring. The interventional plan was evaluated based on these measurements. The central atrium, the thinnest portion of the fossa ovalis, was chosen for puncture of the interatrial septum. For patients with patent fossa ovalis, implantation was performed *via* the fossa ovalis. To avoid elastic retraction of the interatrial tissues or restoration of irregular fissures, the thicker muscular region of the interatrial septum was not chosen. Adequate regional predilation was generally carried out prior to device implantation, which was key to achieving the goal of creating the intended fenestration size. A balloon 2 mm larger than the diameter of the interatrial shunt device was chosen. Appropriately sized interatrial shunt devices and individualized device types were selected based on the preoperative condition of the patients and haemodynamic measurements. The basis for selecting types of shunt device included body weight and body mass index of the patients, severity of symptoms, the amplitude of rise in the left atrium pressure, left atrium-right atrium pressure gradient, severity of right cardiac insufficiency, magnitude of the reduction of post-implantation left atrium pressure and left–right pressure gradient, and severity of systemic-to-pulmonary shunt. The introducer sheath was entered along the pre-moulded hard guide wire, and the fully degassed interatrial shunt device was assembled. The introducer sheath was manipulated to release the shunt device on both sides of the interatrial septum, and then the implant position and shunt effect were immediately confirmed by ultrasonography. The diameter of fenestration was measured post implantation, and cardiac catheter examination was carried out to assess whether the intended fenestration size was achieved.

If the fenestration size was smaller than intended, balloon dilation was performed or the device was retrieved for a larger shunt device. If the fenestration size was larger than intended, a smaller shunt device was used to replace the implant. Aspirin was used for at least 12 months postoperatively, and for those requiring anticoagulation (such as in patients with lower limb thrombosis or atrial fibrillation), warfarin was recommended for at least 12 months.[17] The main steps performed under X-ray irradiation are shown in *Figure 2*, and a video link for simulating the procedure is also provided.

## Haemodynamic measurements

Echocardiography and digital subtraction angiography (DSA) were performed during the operation to determine whether the shunt device was properly positioned. Echocardiography was performed before and 6 months after shunt device implantation to measure the diameter of the left atrium, the right ventricle, and the right atrium as well as the diameter of the left ventricle.[18] Mitral regurgitation and tricuspid regurgitation were also evaluated by echocardiography and


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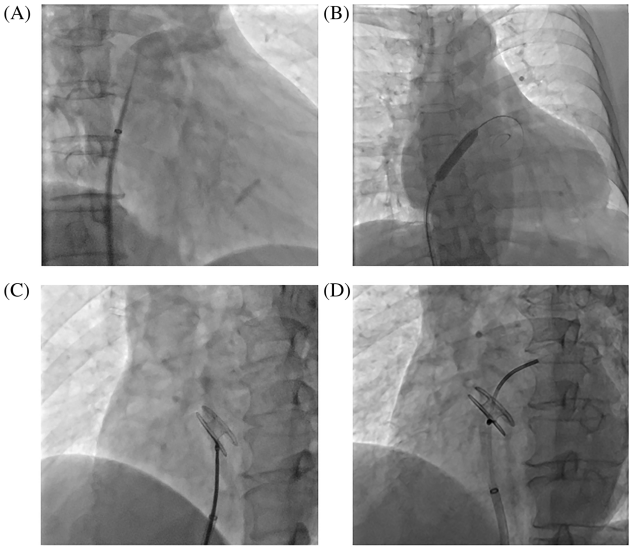
**Figure 2** D-shant implantation process. (A) Atrial septal puncture: pulmonary vein and left atrium were visualized by angiography after atrial septal puncture. (B) Balloon dilation: the hard wire was inserted into the left atrium and adequate regional predilation was generally carried out by using high pressure balloon. (C) Release of the D-shant: the left and right atrial discs of the shunt were released by controlling the introducer sheath and delivery wirerope and the shunt device was clamped on both sides of atrial septum (the method is similar to that of atrial septal defect occluder). (D) Pressure measurement after release: after the shunt was implanted, the right cardiac catheter was performed, and the left atrial pressure was measured by the catheter through the shunt hole.




was divided into 4 grades from 0 to 4 according to previous study.[19] At the time points before surgery and 6 months after surgery, left atrial end-diastolic volume, right atrial end-diastolic volume, and left ventricular end-diastolic volume as well as right ventricular end-diastolic volume were measured by MRI. Left ventricular ejection fractions (LVEFs) and right ventricular ejection fractions were also calculated. Cardiac catheterization was performed 6 months post-implantation to exam the systolic pressure of the pulmonary artery.

## Invasive oximetry using Ficks principle

Haemodynamic calculations, including pulmonary blood flow (Qp), systemic blood flow (Qs), and systemic-topulmonary ratio (Qp/Qs), were performed using the following standard, Fick principle: Qp/Qs = (SaO2 − SvO2)/(SpvO2 − SpaO2).

## Statistical methods

The statistical analysis was performed using SPSS 18.0 software (SPSS Inc., Chicago, IL, USA). Measurement data were expressed as mean ± SD. The measurement data meeting the normal distribution are compared by Student's t test. $P < 0.05$ was considered statistically significant.

# Results

A total of six patients (3 women and 3 men) met the eligibility criteria and were included in the study. The mean age was 57.83 ± 12.66 years, and mean body weight was 63.75 ± 9.45 kg. All patients had NYHA Class III–IV manifestations at baseline. Of the six patients enrolled, one case was a heart failure with preserved ejection fraction patient with ischaemic cardiomyopathy after myocardial infarction. Among the other three HFrEF patients, two cases were diagnosed with dilatated cardiomyopathy and one case was diagnosed with dilatated cardiomyopathy post percutaneous coronary intervention (PCI) for coronary heart disease. The condition of the rest two patients was dilatated cardiomyopathy with extracorporeal membrane oxygenation (ECMO) as a bridge to cardiac transplantation. Patients No. 1 to 5 received shunt device implantation in the ventricular hybrid surgery room. Patient No. 6 received a shunt device in the DSA operating room. Patient No. 6 received ECMO assistance at bedside followed by shunt device implantation. Patient No. 6 and No. 5 received ECMO assistance (A-V mode). Patient No. 5 received a donor-matched heart transplant 21 days after shunt device implantation. Patient No. 6 received a donor-matched heart transplant 9 days after shunt device implantation. The mean operative time was 22 ± 15 min. No instrument dislodgement occurred during the operation. In addition, no pericardial effusion, valvular injury or other complications occurred during the operation. Patient No. 1 with HEpEF received an 8 mm shunt device, Patients No. 2 to 4 with HErEF received a 6 mm shunt device, and Patients No. 5 and 6 received a 10 mm shunt device, respectively. Patients No. 1 to 4 completed 6 months of follow-up. Patients No. 5 to 6 were not evaluated by ultrasound after heart transplantation because of heart transplantation, but all patients survived the 6 months of follow-up. Baseline measurements of patients were shown in *Table 1*.

Clinical manifestations improved to various extents over the 6 months, and no aggravation occurred. No paradoxical embolism was reported. Postoperative follow-up examination of Echocardiography and DSA suggested that the shunt device was correctly positioned in all patients and that the shunt trajectory was unobstructed. The fenestration size showed no change from previous measurements on echocardiography. Echocardiography before and 6 months after shunt device implantation revealed no significant difference in the diameter of the left atrium, the right ventricle, and the right atrium ($P > 0.05$) while the diameter of the left ventricle decreased from 6.40 ± 0.57 mm to 5.03 ± 0.73 mm, significantly ($P < 0.05$). The diameter of the left ventricle retracted an av-

**Table 1** Patient characteristics of the 6 included patients

| Items | Case 1 | Case 2 | Case 3 | Case 4 | Case 5 | Case 6 |
|---|---|---|---|---|---|---|
| Age (year) | 47 | 69 | 73 | 57 | 40 | 61 |
| Gender | Female | Female | Male | Female | Male | Male |
| Weight (kg) | 57 | 61 | 68 | 71.5 | 75 | 50 |
| High (cm) | 158 | 162 | 170 | 165 | 170 | 166 |
| BMI ($kg/m^2$) | 22.8 | 23.2 | 23.5 | 26.26 | 25.95 | 18.14 |
| BSA($m^2$) | 1.60 | 1.67 | 1.82 | 1.82 | 1.91 | 1.57 |
| Cause (aetiology?) | CHD | DCM | DCM | CHD | DCM | DCM |
| Classification | HFpEF | HFrEF | HFrEF | HFrEF | HFrEF | HFrEF |
| Critical condition | No | No | No | No | Yes | Yes |
| Smoke | No | No | No | No | No | Yes |
| Alcoholism | No | No | No | No | No | Yes |
| F/H of CVD | No | No | No | No | No | No |
| Hypertension | No | No | No | Yes | No | No |
| Diabetes | Yes | Yes | Yes | No | No | Yes |
| CBD | No | No | No | No | No | No |
| AF | No | No | No | No | No | No |
| RI | No | No | No | No | No | Yes |
| PVD | No | No | No | No | No | No |
| ECMO | No | No | No | No | Yes | Yes |

AF, atrial fibrillation; BMI, body mass index; CBD, cerebrovascular diseases; ECMO, extracorporeal membrane oxygenation; F/H of CVD, family history of cardiovascular disease; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; PVD, peripheral vascular disease; RI, renal insufficiency.

**Table 2** Comparison of echocardiography before and 6 months after shunt implantation

| Case number | LAD (mm) | | RAD (mm) | | LVD (mm) | | RAD (mm) | | MR (grade) | | TR (grade) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months |
| 1 | 5.0 | 4.8 | 3.2 | 3.4 | 5.6 | 5.6 | 3.5 | 3.6 | 0 | 0 | 0 | 0 |
| 2 | 3.4 | 3.5 | 3.2 | 3.5 | 6.7 | 4.3 | 4.3 | 4.0 | 3 | 1 | 1 | 1 |
| 3 | 5.2 | 5.0 | 4.0 | 3.8 | 6.4 | 5.7 | 4.1 | 4.1 | 4 | 1 | 3 | 2 |
| 4 | 4.8 | 4.9 | 3.4 | 4.1 | 6.9 | 4.5 | 4.8 | 4.9 | 3 | 0 | 1 | 1 |
| 5 | 5.9 | — | 4.1 | — | 9.0 | — | 5.7 | — | 4 | — | 3 | — |
| 6 | 6.6 | — | 4.8 | — | 8.9 | — | 5.0 | — | 3 | — | 2 | — |

BAS, baseline; LAD, left atrial diameter; LVD, left ventricular diameter; RAD, right atrial diameter; RVD, right ventricular diameter; MR, mitral regurgitation; TR, tricuspid regurgitation; 6 months, 6 months post-operation.

erage of 17%. In addition, mitral regurgitation was obviously lessened, and the severity was reduced by at least two units in three mitral regurgitation patients. No apparent change was observed in tricuspid regurgitation (*Table 2*).

According to MRI, the mean LVEF was 27.67 ± 14.39%, and the mean left ventricular end-diastolic volume was 244.00 ± 99.11 mL. MRI at 6 months after shunt device implantation showed a significant reduction in the average volume of the left ventricle compared with the left ventricle before implantation (182.00 ± 27.02 mL vs. 125.75 ± 16.11 mL, $P < 0.05$). There was a rise in LVEF, but this difference was not significant ($P > 0.05$) *Table 3*.

Haemodynamic changes suggested that there was an approximately 43% reduction in the mean left atrium pressure. There was no significant difference in changes in the right atrial pressure or right ventricular ejection fraction ($P > 0.05$). There was also significant improvement in clinical indicators of cardiac function at 6 months post shunt device implantation ($P < 0.05$). The left atrium pressure or pulmonary capillary wedge pressure (PCWP) decreased significantly postoperatively than that before implantation (31.83 ± 11.55 vs. 18.00 ± 5.51 mmHg, $P < 0.05$) (shown in *Table 4*).

Cardiac catheterization at 6 months post-implantation showed a reduction in the systolic pressure of the pulmonary artery, but the difference was not significant ($P > 0.05$). Three patients changed from NYHA Grade III to Grade I or II post-implantation. Cardiopulmonary function determination showed an increase in both peak oxygen uptake and percentage predicted value. There was also an increase in 6 min walk test (6MWT) and the Kansas City Cardiomyopathy Questionnaire (KCCQ). A reduction was found in N terminal pro B type natriuretic peptide (NT-proBNP) (*Table 5*).

## Discussion

Heart failure is a common manifestation of the terminal stage of cardiomyopathies of various aetiologies. Epidemiological data showed that in the United States alone, 6.2 million


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**Table 3** Comparison of MRI before and 6 months after shunt implantation

| Case number | LAEDV (mL) | | RAEDV (mL) | | LVEDV (mL) | | RVEDV (mL) | | LVEF (%) | | RVEF (%) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months |
| 1 | 135 | 120 | 70 | 76 | 143 | 129 | 66 | 71 | 50 | 53 | 40 | 38 |
| 2 | 77 | 80 | 82 | 88 | 195 | 130 | 102 | 85 | 34 | 39 | 42 | 40 |
| 3 | 136 | 127 | 105 | 96 | 186 | 141 | 94 | 88 | 29 | 39 | 40 | 38 |
| 4 | 107 | 105 | 85 | 96 | 204 | 103 | 110 | 125 | 29 | 34 | 35 | 36 |
| 5 | 133 | — | 104 | — | 388 | — | 138 | — | 11 | — | 26 | — |
| 6 | 156 | — | 111 | — | 348 | — | 133 | — | 13 | — | 28 | — |

BAS, baseline; LAEDV, left atrial end-diastolic volume; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fractions; RAEDV, right atrial end-diastolic volume; RVEDV, right ventricular end-diastolic volume; RVEF, right ventricular ejection fractions.

**Table 4** Haemodynamic changes of cardiac catheterization before and 6 months after shunt implantation

| Case number | LAMP/PCWP (mmHg) | | RAMP (mmHg) | | LVSP (mmHg) | | RVSP (mmHg) | | PASP (mmHg) | | TPR (woods) | | Qp/Qs | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months |
| 1 | 17 | 11 | 6 | 7 | 125 | 130 | 22 | 20 | 23 | 22 | 5.1 | 4.6 | 1 | 1.2 |
| 2 | 26 | 16 | 7 | 7 | 137 | 126 | 55 | 43 | 54 | 43 | 8.3 | 7.7 | 1 | 1.3 |
| 3 | 32 | 18 | 7 | 8 | 126 | 120 | 65 | 41 | 65 | 40 | 10.3 | 6.3 | 1 | 1.4 |
| 4 | 26 | 15 | 8 | 6 | 130 | 120 | 43 | 37 | 40 | 37 | 9.4 | 4.4 | 1 | 1.3 |
| 5 | 49 | 27 | 7 | 7 | 103 | 105 | 69 | 40 | 68 | 40 | 15.0 | — | 1 | 1.4 |
| 6 | 41 | 21[a] | 7 | 8[a] | 98 | 100[a] | 73 | 38[a] | 73 | 38[a] | 21.8 | — | 1 | 1.4[a] |

BAS, baseline; LAMP, mean left atrial pressure; LVSP, left ventricular systolic pressure; PASP, pulmonary artery systolic pressure; PCWP, pulmonary capillary wedge pressure; Qp/Qs, pulmonary-to-systemic blood flow ratio; RAMP, mean right atrial pressure; RVSP, right ventricular systolic pressure; TPR, total pulmonary resistance.
[a]Measurement immediately after operation.

**Table 5** Changes of clinical cardiac function indexes before and 6 months after shunt implantation

| Case number | NYHA classification | | $VO_2$ peak (mL/(kg·min)) | | Percentage of predicted peak $VO_2$(%) | | 6MWT(m) | | KCCQ | | NT-proBNP (ng/mL) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months | BAS | 6 months |
| 1 | II | I | 70 | 76 | 87 | 86 | 428 | 472 | 80.91 | 83.1 | 73 | 80 |
| 2 | III | II | 82 | 88 | 36 | 50 | 375 | 439 | 40.00 | 56.6 | 926 | 632 |
| 3 | III | I | 105 | 96 | 43 | 82 | 397 | 466 | 50.91 | 79.2 | 733 | 218 |
| 4 | III | II | 85 | 96 | 48 | 55 | 403 | 440 | 49.09 | 66.5 | 204 | 149 |
| 5 | IV | — | 104 | — | — | — | — | — | 40.0 | — | 10 230 | — |
| 6 | IV | — | 111 | — | — | — | — | — | 30.6 | — | 30 000 | — |

BAS, baseline; KCCQ, The Kansas City Cardiomyopathy Questionnaire; NT-proBNP, N terminal pro B type natriuretic peptide; NYHA, New York Heart Association;$VO_2$ peak, peak oxygen uptake; 6MWT, 6 min walk test.

adults have heart failure.[20] In China, because of its much larger population size, the number of patients with heart failure was estimated to exceed 10 million.[21] Without effective therapy, the 5 year survival rate of chronic heart failure was lower than 50%, and the 5 year mortality rate of acute heart failure reached 60%.[5] The clinical manifestations of heart failure in patients are mainly due to elevated PCWP and left atrial pressure, leading to congestion of the pulmonary vascular bed. The amplitude of rise in PCWP also positively correlates with clinical manifestations, long-term mortality rate, and prognosis.[22] These patients often develop left atrial overload and pulmonary congestion, leading to decreased exercise tolerance. Therefore, reducing the systemic pressure of the left heart in patients has become a potentially effective therapeutic target. Based on this mechanism, and emerging interatrial shunt devices have come into clinical use.

Currently, interatrial shunt devices are still in their clinical development stage globally. Currently, there are three products IASD,[23] V-Wave,[24] and AFR[25] obtained CE Certification. Early exploratory studies of heart failure populations with reduced ejection fractionation were also undertaken simultaneously among various products. Real-world post-marketing clinical application studies REDUCE LAP-HF III and AFteR Registry Follow-up Study have also been initiated.[26] A previous study has suggested that shunt can actually act as a pressure regulator.[27] We concluded that this was because the theoretical basis of atrial shunt was inferred from the previous study on the natural history of small atrial septal defect. It could re-

duce the left atrial pressure at rest and during exercise without significantly reducing cardiac output or leading to right ventricular failure or pulmonary hypertension.

In the current study, we presented an interatrial shunt device with a novel design that could be used for the treatment of different stages of heart failure. The initial results were very satisfactory, and there were no severe complications such as death, device migration, valvular injury, or paradoxical emboli. In the current study, the structure of the double disc buckle-shaped mesh plug woven from nickel-titanium alloy allowed effective anchoring of the shunt device on the interatrial septum. Because of its metal shape-memory property and an inner hollow structure, the shunt device could enter a smaller introducer device. The currently available D-shant atrium shunt devices come in four dimensions for various conditions, the largest had a diameter of 28–10 mm and only requires an 8F introducer sheath for loading, which was different from the IASD device[28] that requires a 16F introducer system, the V-Wave[18] that requires a 14F introducer system, and AFR[29] that requires a 12-14F introducer system. An introducer system with a smaller diameter can be utilized in patients with femoral veins of different diameters and simultaneously lessen the risk of injury by the introducer system. More importantly, the device had a unique eccentric design in the rivet. The disc surface of the left atrium had no rivet (using single-side weaving technology), preventing a possible left atrial thrombus from attaching to the rivet. The disc surface of the right atrium had an oblique rivet. The advantage of this design was that even if the shunt device becomes completely detached from the introducer sheath, the rivet could still be easily captured by the snare. This design was important as the haemodynamics of the atrium were changed as a result of shunt device implantation. In the future, if haemodynamic changes are not ideal, the device can be rapidly retrieved percutaneously. In addition, the core technology of the D-shant atrium shunt device has strengthened radial support of shunt fenestration. This key measure can effectively avoid the gradual progression of epithelization of shunt fenestration.

There were also some limitations. First, the sample size of the study was small. Second, patients included in the present study were all from a single centre, which could result in some selection bias. Third, the period of follow-up was relatively short in this study. Therefore, in order to improve the quality of research results, studies with more scientific sample size and more comprehensive design are still in need.

## Conclusions

The novel D-shant atrium shunt device in the treatment of chronic heart failure revealed good safety and capability of effectively improving the clinical symptoms of heart failure in patients, reducing the degree of mitral regurgitation and improving the cardiac function of patients. Medium-term and long-term clinical follow-up can help confirm these results.

## Conflict of interest

None declared.

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## Conflict of interests

The authors declare that they have no competing interests.

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